



TELEPHONE CONTACT REPORT

DATE: 2/21/02

IRB#: PPD1-01-191

INVESTIGATOR NAME: Anne Kirkman-Campbell, MD

(Check appropriate item)

Sponsor
CRO

☐
☒

SMO
SITE

☐
☐

Subject
Other

☐
☐

Specify:

IRB STAFF MEMBER TAKING CALL: Sarah Wallace

A monitor who would like her name confidential called me today about patient concerns she had with Dr. Campbell's site. She has reviewed 50 of the 400 files and some of her concerns are listed below.

- Site has enrolled over 400 subjects in a small, rural Alabama town.
- Several charts show patients came to the office for back pain and other problems and then seem to have been altered. In the same location on all charts, in different color ink someone has written acute exacerbation of bronchitis.
- She stated the site had several informed consent issues. Many of the dates seemed to have been changed. Some of the initials on the pages of the IC look to have been written by someone else. She has even found some that the signature looks to be forged.
- She also asked us to check into Dr. Kirkman-Campbell's credentials as she has told people in her office different things.
- She also said she knew that Dr. Kirkman-Campbell is in the Summit trial for which we are the IRB.
- In her opinion, the investigator is manipulative and concerned only with making money.
- She thinks that some subjects are not actually receiving drug and certainly that no telephone follow-up calls are being made.